REMARKS

In an office action mailed March 18, 2002, the Examiner has objected to claims 7 and 8 under 37 CFR 1.75(c), and rejected claims 1-13 and 19-28 under 35 USC §112, second paragraph, claims 1-14 and 18-28 under 35 USC §102(b) and claim 15 under 35 USC §103(a). In response thereto, Applicants submit the above amendments and the following remarks.

By this amendment, claims 1-13 and 19-28 have been cancelled and new claims 29-45 have been added. Accordingly, claims 29-45 are pending in the application.

The Invention

The invention relates to a method for improving the benefits of a vaccination. Applicants have discovered a novel method for inducing or stimulating T-helper cell response in a human or an animal against at least one antigen.

According to the claimed method, a first vaccine composition comprising the antigen and a first vector is administered to the animal or human. Next, a second vaccine composition comprising the antigen and a second vector is administered. The first and second vectors are different from each other.

The claimed invention has the advantage that both humoral and cellular immunity can be obtained. Moreover, a T-helper cell response is capable of generating long term memory for both cellular and humoral immunity, therefore, improving the overall performance of the vaccination.

Priority

Applicants would like to thank Examiner Mosher for acknowledging the claim to priority based on a European application, and for pointing out that a certified copy of the priority document had not been filed yet. Filed herewith is a certified copy of the priority document EP 992000256.8.

Claim Objections

In the office action, claims 7 and 8 have been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. By this amendment, claims 7 and 8 have been cancelled and new claims 29-45 added. New claims 31-33 correspond to claims 7 and 8.

Claim 31 depends on claim 29 and limits claim 29 by defining the antigen as a antigen of a virus. Claims 32 and 33 depend on claim 31 and further limit claim 31 by defining the virus as a lentivirus or a hepatitis C virus (claim 32), and causing a temporary or long lasting immune impairment (claim 33).

Accordingly, Applicants respectfully submit that the above claim objections are rendered moot.

Rejections Under §112

Claims 1-13 and 19-28 have been rejected under §112, second paragraph as being indefinite in the recitation of "sequential administration, " and "preferably." By this amendment, the rejected claims have been cancelled and new claims 29-45 have been added.

New claims 29-45 more clearly define the sequential administration required by the claimed method.

Rejections Under §102

In the office action, claims 1-14 and 18-28 have been rejected under §102(a) as being anticipated by Hanke et al. Hanke et al. disclose a method for specifically inducing immune responses mediated by cytotoxic T lymphocytes (CTL), i.e. CD8+ T cells. The method of Hanke et al. utilizes a peptide of 8-10 amino acid residues in length and a modified vaccinia virus Ankara (MVA) as a delivery vehicle.

In contrast, the claimed invention is directed to a method for specifically inducing T-helper (Th)-type response, i.e. CD4+ T-cells. In order to induce a Th-type response according to the invention, the peptides utilized typically need to be at least 12 to 16 amino acid residues long.

It is well known in the art of immunology that peptides ranging from about 12 to 25 amino acid residues are recognized by, and stimulate, Th-type immune response. It is also well known in the art that CTLs recognize short peptides (from about 8-10 amino acid residues). Therefore, based on these known antigenic properties, the 8-10 amino acid residue peptide utilized in Hanke et al. would not be recognized by the Th-type cells targeted in the claimed invention.

The Examiner admits that Hanke et al. do not explicitly discuss Th-type response, but contends that this is a inherent feature of the MVA vector and vaccine delivery methods used in Hanke et al. Applicants respectfully disagree.

In order to rely on a theory of inherency, "the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original).

As mentioned above, Hanke et al. provide a method of inducing a specific immune response, namely, a CD8+ T-cell response. Hanke et al., however, do not teach inducing a Th-type immune response. Furthermore, due to the size requirement for antigenic peptides, the peptide of 8-10 amino acid residues disclosed in Hanke et al. would not be expected to induce a Th-type response.

Consequently, the Examiner has not provided evidence that inducing Th-type response according to the claimed invention would necessarily, or even possibly, flow from the teachings of Hanke et al. Applicant's respectfully request the rejection of the claimed invention under §102, based on principles of inherency be withdrawn.

Rejections Under §103

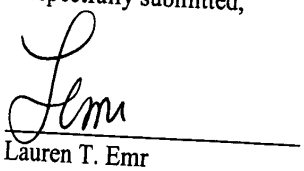
Claim 15 has been rejected under §103 as being unpatentable over Hanke et al. Hanke et el. differs from claim 15 in that animals were vaccinated, not humans. The Examiner contends that the stated goal of Hanke et al. is to develop vaccines for humans, therefore, the invention as a whole is prima facie obvious.

As mentioned above, Hanke et al. do not teach a method for inducing Th-type response. In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicants' have demonstrated the importance of utilizing specifically tailored peptides in order to induce a Th-type response. Upon reading the teachings Hanke et al., all of Applicants' claimed limitations are not taught or suggested. Therefore, based on the foregoing discussion, Applicants' claimed invention is not obvious over Hanke et al.

In light of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, she is invited to contact the undersigned at her convenience.

Respectfully submitted,



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